PART II

PLAINTIFFS' EXHIBITS

EXHIBIT 6

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CASE NO. 07-CV-1359 (HAA)

CHAYA GROSSBAUM and MENACHEM GROSSBAUM, her spouse, individually and as guardians ad litem of the infant ROSIE GROSSBAUM,

Plaintiffs,

vs.

GENESIS GENETICS INSTITUTE, LLC, of the State of Michigan, MARK R. HUGHES, NEW YORK UNIVERSITY SCHOOL OF MEDICINE and NEW YORK UNIVERSITY HOSPITAL CENTER, both corporations in the State of New York, ABC CORPS, 1-10, and JOHN DOES 1-10

Defendants.

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DEPOSITION UPON ORAL EXAMINATION OF:
MARK R. HUGHES, M.D.

TRANSCRIPT of the deposition of the witness, called for Oral Examination in the above-captioned matter, said deposition being taken pursuant to Notice, taken by and before KATHLEEN HAGEN, a Notary Public and Certified Shorthand Reporter of the State of New Jersey, at the law offices of NUSBAUM, STEIN, GOLDSTEIN, BRONSTEIN & KRON, P.A., 20 Commerce Boulevard, Succasunna, New Jersey, on Thursday, February 19, 2009, commencing at 10:30 a.m.

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M-A-R-K R. H-U-G-H-E-S, M.D., Ph.D., having offices at Genesis Genetics Institute, LLC, 5555 Conner Avenue, A22064, Detroit, Michigan, 48213, called as a witness, having been duly sworn, was examined and testified as follows:

DIRECT EXAMINATION BY MR. STEIN:

Q Dr. Hughes, as you know, we're here to take your deposition. I take it that you have previously submitted to a deposition?

A Yes.

Q About how many occasions?

A Twice.

Q Well, before I ask you about those, permit me to give you some guidelines and instructions, which we should operate under during this question and answer session. First, I should tell you that my questions and your answers are being recorded by the lady who sits to my right and your left, who is a Certified Shorthand Reporter, and if this case goes to trial, what you say here may be used at trial, so you should treat this question and answer session with the same onus as if you were giving testimony in open court, even though we're here in the law office. Do you understand that?

A Um-hum, I do.

Texas at this time, is that right?
A It's in some limbo state of some type, I don't know what it's actually called. I have to continue to do CME credits, which I wasn't doing, so they put me in some inactive state of some type.
Q And you have not sought licensure in any other state, is that correct?
A That's correct.
Q Well, has your laboratory been referred for analysis of genetic materials from NYU, prior to the time of the Grossbaum family?
A Many times.
Q Can you give me some indication of the number, approximately?
A Certainly 50.
Q Over what period of time?
A I don't remember when it started, but through now.
Q Okay. And when you estimate 50, are you estimating it 50, including right up to the present time?
A Yes.
Q Other than the Grossbaums, are you aware of any other laboratory studies that you did, that resulted in a CF baby being born to a couple?

A Yes.
Q On how many occasions?
A Four.
Q Can you tell me when the most recent occasion was?
A No, I don't remember the date.
Q Have any of those four occasions occurred since the Grossbaum baby was born?
A Yes.
Q Can you tell me how many of those four occurred since the Grossbaum baby was born?
A One, I think, I'm pretty sure.
Q Okay. And the Grossbaum baby is one, and are you suggesting that there were two others, prior to the Grossbaum baby being born?
A I believe so, yes.
Q Okay. Now, other than these four, I take it that -- withdraw the question.
I take it that the work of doing PGD testing has taken place, in your experience, since the date that you opened Genesis Genetics, when you left Georgetown, is that right?
A Oh, it's been going on since I invented the technology, 19 years ago.
Q Okay. And how many babies have come to

your attention as being born with cystic fibrosis, that you did PGD testing on?
A Four, I believe.
Q And these four are the four you mentioned?
A Yes.
Q And how many babies would you say you tested for cystic fibrosis mutations, in doing PGD testing, in total, over the time that you've been doing this work?
A I do not know, but over 1000.
Q Is there a particular ethnic group of people who have a higher incidence of cystic fibrosis mutations than others?
A Caucasions.
Q Now, it's reported that the testing for the screening testing for the CSF gene is 97 percent effective within Ashkanazi Jews, is that correct?
A Well, it's variable, depending on who's doing the testing and how many different mutations they're testing for, unless you actually sequence the gene entirely, you can't have a perfect test, and even then, you don't have a perfect test, but you reduce that percentage closer and closer to zero risk of having a mutation, the more mutations you test for. So some laboratories test for 20, some test for 40, some test

for 90, it depends on where the sample is sent.
Q Okay.
A Now, that's the risk of finding a mutation in the gene. So I'll give you a little biology lesson. If you screen the woman, and you don't find a mutation with a test that has a 95 percent accuracy, and you screened the man, and you don't find a mutation that has that, has a 95 percent accuracy, then the chances that both of them have a mutation in the 5 percent become quite small, so their background risk goes from 1 in 25 that the general population of Caucasians have a cystic fibrosis mutation substantially less, so their risk of having a child with CF goes from 1 in 2500 to significantly less, but not zero.
Q Okay. In connection with your work doing PGD testing, is the religious background of the subject parents ever taken into consideration?
A No, not at all.
Q And you don't solicit that information, is that correct?
A No, it's -- no, not at all. In fact, I sometimes worry it would be illegal to start asking personal questions like that for a laboratory, so we don't. The only time I find out if a patient, for example, is Jewish is that there's a large charity in

don't have their particular DNA?
A Yes, yes, we do.
Q You get the DNA weeks before?
A Oh, yes, sometimes months.
Q And that's based on the blood samples you're sent?
A Yes, or cheek swab samples now.
Q Good. Were they blood samples back in 2004?
A Yes.
Q And then you -- from the blood samples, you ascertain the nature and character of their DNA, and then you use the formulas to the point that you can, and then you apply a trial and error method to design a test for this particular couple, is that what you're saying?
A That's correct.
Q Now, in your page 2 of your pre-case phone review, you mention that you have written, if you follow with me in the third sentence down on the page, and I quote, "You do not need PGD; remember, you can just get pregnant and have a prenatal test like CV or amnio, there are great OB's that do it in New York who could do this for you."
A The docs, d-o-c-s, doctors.

Q Do you recall telling that to the Grossbaums?
A I don't personally recall saying it, but I'm sure I did.
Q Okay. And did you inquire of them, at that time, whether they had any problem with amnio or CVS?
A There was no indication at any time that they had a problem with CVS or amniocentesis, because if they had said they wouldn't do that, I wouldn't have taken their case, and NYU knows that, and so do all the programs, we -- we must -- we must be monitoring the integrity of this complicated technology more frequently than every 9 months. If a couple says to me, How reliable is what you're doing? And I say, Well, pretty good, but we haven't looked for 9 months, that's not very reassuring, so from the beginning of this research project, we have always required that a follow-up prenatal test be performed, and if the patient doesn't want to do that, that's fine, because we can't take care of them.
Q Well, I'm sure, in the course of your experience, people have told you that -- well, withdraw that.
The purpose of doing a CVS or amnio is to

facilitate aborting a CF baby, is that true?
A No.
MR. HAMAD: Objection to form.
Q Well, what would be the purpose of doing an amnio and CVS test?
A To find out the integrity of the single cell testing that we're doing on this project. As a scientist, we have to be monitoring this. If we didn't, we would be -- it would be not scientific, and it would certainly be unethical.
Q So from your point of view, doing the CVS testing or the amnio testing of the fetus is purely for the scientific confirmation of the validity of your PGD test?
MR. HAMAD: Objection. Mischaracterizing the prior testimony.
Q Do you understand the question?
A There are many reasons to having a prenatal test. It's state of the art medical care of obstetrics, and we want to monitor the quality of our data, knowing that it isn't perfect. And we need to monitor it frequently, and the most frequent we can do it is at a CVS or an amniocentesis stage, so that's when we require the testing to be done. What you do with the information from an amnio or CVS is completely

up to you, of course, but the test itself has to be performed, we have it in our informed consents, we talk about it -- we mention it, and I got no indication I would have written it down, and I would not have taken this case.
Q There are from -- aside from the scientific need for PGD testing validation, the people involved would see the rationale for that, to determine whether they want to continue to give birth to a CV -- to a cystic fibrosis baby, wouldn't that be your expectation?
MR. LEUCHTMAN: I object to the form of the question.
MR. HAMAD: I join in that objection.
MR. LEUCHTMAN: Vague, ambiguous, and speculative.
MR. HAMAD: I join in that objection.
Q Do you understand the question?
A Please repeat it.
MR. LEUCHTMAN: Better yet, rephrase it.
Q When you say you require this testing by the CV and amnio testing by the mother of the fetus, do you have a discussion that the purpose of your requirement is for -- solely for PGD testing validation?

MR. LEUCHTMAN: Wait, wait, wait. Before you answer it, I'm going to object to the form of question, mischaracterizing previous testimony. I don't think he has said that integrity of test results is the sole purpose of amnio or CVS. He has said, in fact, although he hasn't been interrogated about what the other factors are, that it's multi-factorial, that there are a number of reasons why he does it or has that requirement, so the sole aspect of that question mischaracterizes the testimony.

Q Well, let me ask you this. What are the other reasons that you require amnio and CV testing, besides scientific validation of PGD testing?

MR. HAMAD: Objection. I think he also gave another reason, besides scientific validation of testing.

Q I'm asking, what are they?

A From my personal perspective of this project, that's the only reason, but a clinician might have an instruction with the patient about other reasons why this might be a good idea, as a chromosome abnormality, because of all kinds of other things that you can find with those sorts of tests, you can have the right doctors present at the time of delivery, if there's a

problem that you can head off at the pass, but from a laboratory perspective, our requirement is in order to monitor the data and it's a prerequisite of enrolling in the program.

Q Is there any form that you provide the family, in which they sign to agree to do this as a condition of your doing the testing?

MR. LEUCHTMAN: Do what, undergo amnio or CVS?

Q Right.

A Well, we talk about the fact that it's necessary, and there's an informed written consent that has it in there, and they sign the consent, and most patients don't ever bring it up as an issue, so it's just mentioned that you have to have it, and I'm assuming they're being honest and not deceptive. I mean, I'm halfway across the country talking to a patient that I wouldn't have to talk to, we go the extra mile in our laboratory to try to make sure that everything is on queue, and if a couple is going to be deceptive and dishonest with me, or dishonest, I don't know which, it's not my position to know, we just simply are very polite, but we tell them, I'm sorry, we can't take care of you.

Q Overall, aside from the limitation of CF

mutations in your -- in the entire spectrum of your testing, how many cases have you had where there was a misdiagnosis through PGD testing?

A There's -- we're not sure about one, so they're either 12 or 13 over the course of 15 years. We thought there was 14, but it turns out we could prove a couple got pregnant on their own, so it didn't count, so it was an error or at least it looked like an error, but in DNA technology, we can do a DNA fingerprint on an embryo when we do the test so we know which embryo made the baby, and we know that the right one was put in, and we know that the baby that they've got wasn't any of the embryos that they had in the incubator, but that's happened in the last four or five years of technology development. Back in 2003-4, that wasn't available yet.

Q Turning to page 3, there is a line about two-thirds of the way down the page that starts, "Need to follow up with CV and amnio". Do you see that line?

A Um-hum.

Q There is a circle on that line that has some letters inside. Can you tell us what those letters are?

A That says "Evans".

Q What is that, a name?

A Yes, that's a doctor in New York City who is world renowned at CFS and amnios, who has the lowest what -- well, he's as good as it gets, and I don't remember why I put that in there, but probably, I was going to recommend, once they're pregnant, that they go see him, but I don't know why, he's the person I would want them to see. I send other families to them, as well, but in a place like NYU, they have their own internal groups, and so that's probably why I have the question mark, because they'll take care of it for the family separate from me, but if they live in, you know, some little town in Montana, I need to get them to the right place, so I try to assist their genetic counselor in doing that.

Q Now, there's a page in your chart which lists what appears to be the sequencing category listing down with numbers 1 to 20 on the left-hand side. I'll show you the page I have reference to.

A Okay.

Q That looks to me a little bit like a diary of the various activities that your laboratory will undertake, from the point of view of initial inquiry until the baby is born, is that correct?

A Yeah, well, yeah, this has been a table that we've had for a long time, we have found it is

of Polymorphic Markers Flagging the CFTR Gene, A General Approach for Pre-implantation, Genetic Diagnosis of Cystic Fibrosis."
A Okay.
Q And do you recall being aware of that, at the time you did the study for the Grossbaums?
A I don't recall, no.
Q Okay. Were you aware that that type of testing was done at other laboratories, in the United States?
A We were all trying to do it, which is why I wanted to have those embryos, so that we could set genetic phase for the family, and do that. I'm sure that's what I meant by this. See, in order to look at polymorphic markers, you need to have some way to link the marker to the mutation.
Q Do you need certain equipment to do it?
A No, we had the equipment to do it, but we needed to have another sample, so you need a member of the family. If this couple had a healthy child or if this couple had an affected child or a sister or a brother that were carriers that we could get a sample from, the idea would be then to look at those markers and set what's called "genetic phase" to determine whether the marker -- which markers are linked to the mutation.

Q That can't be done just with the specimens received from the mother and father?
A No, you can look at the markers, but they won't mean anything.
Q Okay.
A But, you see, the point was that, if we could get the embryos that were affected, the cystic fibrosis from this couple, we now would have a sample that would have the mutation or not have the mutation, based on these data, based on the sequencing data, and we could then do that kind of thing for this family, which would be if they had to go through this another time, we would then try to develop a better test, using those genomic markers.
Q On the same subject, were you aware of a published article titled, "Improving Clinical Pre-Implantation Genetic Diagnosis for Cystic Fibrosis by Duplex PCR Using Two Polymorphic Markers or One Polymorphic Marker in Combination with the Detection of Delta F508 Mutation"?
A I read lots of papers, we're perfectly aware of all of that technology.
Q That was by Dr. Goosens, G-o-o-s-e-n-s, at the Center for Medical Genetics at the University Hospital & Medical School of Brussels University, are

you familiar with that group?
A Yes.
MR. HAMAD: Can we have the journals, if any, that these articles appeared in? I think you're referencing these articles.
MR. LEUCHTMAN: Could we get copies of them before we leave?
MR. STEIN: sure.
MR. LEUCHTMAN: Thank you. And what are the dates of these articles?
MR. STEIN: Well, the article out of Brussels, Belgium is in Molecular Human Reproduction, Copyright, European Society of the Human Reproduction in Embryology, 2003; the article out of Maastricht is copyrighted by the Human -- it's in the Molecular Human Reproduction, Volume 6, number 5, pages 391 to 396, and the year is 2000.
Q Would that type of testing have reduced the risk of misdiagnosis for these patients?
A If the cause of the misdiagnosis was allele -- allele drop out, if that was the cause of the problem, and if we had a sample that they would give us that would allow us to use the technology, absolutely, it would have helped, and we do that routinely now.

Q Okay.
A If we have a sample, many times, the couple -- there's no other family members that are available or willing to give samples or the couple's keeping it quiet from other members of the family or whatever, but there's reasons why you can't get other samples.
Q Well, did you try to get it from these, this couple, the Grossbaums?
A These technologies were not in routine clinical care, at that time. We were doing them in an attempt to bring them into our laboratory, because we agreed that it looked like this would improve the technology, and with every year, the technology improves, and to measure what we would do in early 2004 with what we could do in 2008 is not reasonable. We -- we would do genotyping, we've been doing that kind of genotyping for years, when you have the proper samples.
Q Did you ask for the samples of the Grossbaums?
A I believe we did.
Q And you didn't get them?
A I believe, I believe they didn't want to give them to us, but I can't be sure.
Q Is there anything in your records to document that?

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

11:00:35

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CHAYA GROSSBAUM and MENCHEN GROSSBAUM, Her Spouse, Individually, and as Guardian ad litem of the Infant, ROSIE GROSSBAUM,

Plaintiffs,

-against- Index No. 07-CV-359

GENESIS GENETICS INSTITUTE, LLC, OF THE STATE OF MICHIGAN, MARK R. HUGHES, M.D., NEW YORK UNIVERSITY SCHOOL OF MEDICINE, and NEW YORK UNIVERSITY HOSPITALS CENTER, both Corporations of the State of New York, ABC CORPORATIONS: 1-10 and John Doe

Defendants.

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132-26 Conduit Avenue
Jamaica, New York
May 4, 2010
10:30 a.m.

DEPOSITION of CHARLES STROM, M.D., PhD., an expert witness on behalf of the Plaintiff herein, taken by the Defendants pursuant to Article 31 of the Civil Practice Law and Rules of Testimony, and Notice, held at the above-mentioned time and place before Valerie Cannata, Shorthand Reporter and Notary Public of the State of New York.

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ALSO PRESENT

WAYNE SALINE, VIDEOGRAPHER
VERITEXT, LLC
STANLEY DICKSON, GENESIS GENETICS

STIPULATIONS

IT IS HEREBY STIPULATED by and between the attorneys for the respective parties hereto that:

All rights provided by the C.P.L.R. and Part 221 of the Uniform Rules for the Conduct of Depositions, including the right to object to any question, except as to form, or to move to strike any testimony at this examination is reserved; and in addition, the failure to object to any question or to move to strike any testimony at this examination shall not be a bar or waiver to make such motion at, and is reserved to, the trial of this action.

This deposition may be sworn to by the witness being examined before a Notary Public other than the Notary Public before whom this examination was begun, but the failure to do so or to return the original of this deposition to counsel, shall not be deemed a waiver of the rights provided by Rule 3116 of the C.P.L.R., and shall be controlled thereby.

The filing of the original of this deposition is waived.

IT IS FURTHER STIPULATED that a copy of this examination shall be furnished to the attorney for the witness being examined without charge.

C. STROM, M.D., PhD.

THE VIDEOGRAPHER: My name is Wayne Saline of Veritext. The date today is May 4, 2010. The time is approximately 11:00. This deposition is being held at the Sheraton JFK located at 132-26 South Conduit Avenue, Jamaica, New York. 11:00:38 11:00:39 11:00:43 11:00:45 11:00:49 11:00:54

The caption of this case is Chaya Grossbaum and Menchen Grossbaum, her spouse individually and as guardians ad litem of the infant, Rosie Grossbaum, in the United States District Court of the District of New Jersey, docket number 07 CV 359. The name of the Witness is Dr. Charles Strom. 11:00:57 11:01:01 11:01:05 11:01:09 11:01:10 11:01:13 11:01:15 11:01:19

At this time, the Attorneys will introduce themselves and the parties they represent, after which our Court Reporter, Valerie Cannata, of Veritext will swear in the Witness and we can proceed. 11:01:21 11:01:21 11:01:24 11:01:28 11:01:31 11:01:32

MR. LEUCHTMAN: Stephen Leuchtman, taking the deposition today on behalf of Genesis Genetics and Dr. Mark Hughes. Also with me is Stanley Dickson, an officer 11:01:34 11:01:36 11:01:38 11:01:41

C. STROM, M.D., PhD.

in Genesis Genetics. 11:01:44

MR. HAMAD: Jay Hamad of the Law Firm of Marshall, Dennehey, Warner, Coleman and Goggin. I'm on behalf of N.Y.U. Defendants. 11:01:46 11:01:46 11:01:48 11:01:49

MR. STEIN: Lewis Stein; Nusbaum, Stein, Goldstein, Bronstein and Kron on behalf of the Plaintiffs and before we swear the Witness, I'd just like to confirm on the record a conversation I had with Counsel for N.Y.U. that Dr. Strom having offered his opinion letter in the case did not mention any standard of care issues as to N.Y.U. He will not be offering any testimony regarding standard of care of N.Y.U. or members of the N.Y.U. community in connection with this deposition. 11:01:50 11:01:53 11:01:56 11:01:59 11:02:03 11:02:05 11:02:10 11:02:12 11:02:15 11:02:18 11:02:22 11:02:23

CHARLES STROM, M.D. PhD., the Witness herein, having first been duly sworn by a Notary Public of the State of New York, was examined and testified as follows: 11:02:36

THE REPORTER: What is your full name?

center. 11:21:41
Q. Who was your boss? 11:21:41
A. Dr. Beverly White. 11:21:42
Q. During that period of time, did 11:21:44
Quest do P.G.D.? 11:21:47
A. No. 11:21:49
Q. How did your responsibilities 11:21:50
change when in June of 2002 you became 11:22:00
the medical director of the genetic testing 11:22:04
center? 11:22:10
A. That was a promotion, so I got 11:22:10
my boss's job and she retired. Actually, she 11:22:12
reported to me for a period of time. 11:22:18
Q. During that period of time, did 11:22:19
you do any P.G.D. or did the lab? 11:22:21
A. No. 11:22:23
Q. So you have not had hands-on 11:22:24
experience or directorial experience with 11:22:28
preimplantation genetics diagnosis since 11:22:33
October, 2002, or before? 11:22:38
A. That's correct. 11:22:40
Q. While you were at Quest, up to 11:22:50
today, have you had teaching responsibilities at 11:22:53
any university? 11:22:56

A. I teach -- I have a faculty 11:22:58
appointment at U.C.S.D. I teach intermittently 11:22:59
there and I also obviously give lectures across 11:23:06
the country. 11:23:09
Q. What do you teach at U.C.S.D.? 11:23:10
A. Everything genetics. 11:23:12
Q. Does this touch on P.G.D.? 11:23:15
A. Sometimes. 11:23:18
Q. What percentage of your 11:23:29
teaching responsibilities involve preimplantation 11:23:31
genetic diagnosis? 11:23:34
A. Probably less than five 11:23:34
percent. 11:23:36
Q. So it's fair to say that during 11:23:41
the time that this case unfolded, which is in 11:23:43
early 2004, primarily, you were not 11:23:49
involved either as a director of a P.G.D. 11:23:54
lab, hands-on with P.G.D. or teaching 11:23:58
P.G.D. to any significant extent? 11:24:03
MR. STEIN: Objection to the 11:24:05
form of the question. 11:24:06
A. No. That wouldn't be true 11:24:07
anyway. 11:24:09
Q. Why not? 11:24:09

A. Because my teaching 11:24:10
responsibilities are different than my 11:24:11
lecturing. 11:24:14
Q. Okay. 11:24:15
A. I lecture around the country 11:24:16
and often give talks on preimplantation 11:24:19
genetics. 11:24:23
Q. In a university setting, your 11:24:23
teaching is less than five percent of P.G.D.? 11:24:26
A. Yes. 11:24:31
Q. How much time do you spend 11:24:32
going around the country lecturing about P.G.D., 11:24:34
per se? 11:24:36
A. About two or three percent of 11:24:36
my time. 11:24:38
Q. Was this true in 2004? 11:24:39
A. Probably more so in 2004. 11:24:44
Q. How much more so? 11:24:47
A. I don't know. 11:24:49
Q. Less than ten percent? 11:24:50
A. I don't know. 11:24:51
Q. Less than 25? 11:24:52
A. I don't know. I just don't 11:24:54
remember. 11:24:56

Q. Well, give me a ballpark 11:24:57
estimate, not a guess. 11:24:58
A. I'm sorry, I just don't 11:24:59
remember. 11:25:01
Q. At all? 11:25:01
A. At all. It's a long time ago, 11:25:02
for me. 11:25:06
Q. So you probably don't remember 11:25:06
the standard of care for preimplantation 11:25:12
genetic diagnosis back in 2004 either? 11:25:15
A. I remember it very well. 11:25:18
Q. But you don't remember how much 11:25:20
of your lecture time was devoted to P.G.D.? 11:25:22
A. No, I don't remember. 11:25:26
Q. Was it less than half then? 11:25:27
A. I don't remember. 11:25:31
Q. When you went to Quest 11:25:34
initially, what were your responsibilities? I 11:25:35
think you started to tell me. 11:25:37
A. I told you. 11:25:39
Q. You did tell me. All right. 11:25:39
What are they now? 11:25:41
A. Now I oversee all of the 11:25:42
genetic testing that goes on in San Juan 11:25:47

Thornhill wrote that article, we had already published several articles in the '90s on multiplex P.C.R. 11:40:15 11:40:18 11:40:22

Q. We being whom? 11:40:22

A. Reproductive Genetics Institute. 11:40:22 11:40:28

Q. Do you believe that a scientist such as yourself or Dr. Mark Hughes has a responsibility to examine and test out ideas and concepts that appear in the literature and not just blindly accept that them? 11:40:28 11:40:28 11:40:35 11:40:35 11:40:41

A. Of course. 11:40:43

Q. And do you agree that by characterizing, again, P.G.D. with duplex P.C.R. as improving, the authors of the article, Goosens, et. al., acknowledge that duplex testing with genome markers was still evolving? 11:40:43 11:40:44 11:40:47 11:40:52 11:40:55

A. No. 11:41:00

Q. You think it was settled science at that time? 11:41:00 11:41:02

A. I think the concept of multiplex P.C.R. for the detection of allele dropout was well established by the year 2000 when I left R.G.I. Other 11:41:02 11:41:04 11:41:12 11:41:18

people began instituting them in their own programs at that point and the Thornhill report was what he had implemented. 11:41:23 11:41:25 11:41:28 11:41:31

Q. Where is Thornhill based? 11:41:32

A. I don't know. 11:41:34

Q. Is he in the United States? 11:41:35

A. No. I think he's in Australia? Australia or England. He speaks with an accent. 11:41:37 11:41:41 11:41:47

Q. Over what course of time did testing using genetic markers develop? 11:41:47 11:41:50

A. It was over the period of about 1992 until 2000 in my laboratory when we actively and intensively investigated the role of link markers in predicting and identifying allele dropout. 11:41:52 11:41:54 11:42:00 11:42:04 11:42:08

Q. That's an eight-year spread. Let me ask you this: During that eight years, what factors slowed the development of genetic marker testing? 11:42:11 11:42:14 11:42:15 11:42:18

A. Nothing. 11:42:20

Q. Nothing at all? 11:42:21

A. No. We just continued to work. 11:42:22

Q. Well, it took eight years to develop it from the time it was first theoretically suggested? 11:42:24 11:42:27 11:42:28

A. It took eight years, I would say, to perfect it. Things don't happen overnight. 11:42:28 11:42:30

Q. That's true, particularly in the area of genetic marker testing? 11:42:38 11:42:41

A. That's right. 11:42:46

Q. So what were the -- well, describe, I guess, since you say there were no obstacles that had to be overcome, describe the eight-year development. What bumps were there in the road, what? 11:42:47 11:42:47 11:42:50 11:42:55 11:42:57

A. Initially we first discovered that allele dropout could be a cause of misdiagnosis in preimplantation genetic diagnosis and that happened in the early years between 1990, 1992. Once -- first we investigated and found out that was the most likely cause of what was happening. Then we had to investigate it in detail, which meant that we had to get skin biopsies, which were removing skin from carriers of patients with genetic 11:42:57 11:43:01 11:43:01 11:43:05 11:43:07 11:43:10 11:43:13 11:43:15 11:43:18 11:43:22 11:43:26

diseases, grow that skin in tissue culture. Take single cells and subject them to a variety of testing to determine what was the rate of allele dropout seen in those cells. 11:43:30 11:43:34 11:43:36 11:43:39 11:43:42

When we established that allele dropout was a recurrent phenomenon, then we had to figure out a way to overcome it and the way that turned out to be -- there were two ways that we eventually evolved to limit the misdiagnosis due to allele dropout and the first was the use of intragenic linked markers. 11:43:44 11:43:46 11:43:50 11:43:54 11:43:57 11:44:01 11:44:03

We developed the linked intragenic markers and we then had to develop the assays. We had to optimize them to work on single cells. Then we had to find patients who had those particular high markers and then we had to develop multiplex P.C.R. in order to look at all of them at once and that was a very tedious procedure that took several years. 11:44:03 11:44:09 11:44:16 11:44:20 11:44:24 11:44:27 11:44:32 11:44:34 11:44:38

Then once we had the system optimized and we had shown that in vitro on skin fibroblasts, we could virtually eliminate 11:44:38 11:44:41 11:44:44

C. STROM, M.D., PhD.

other than control samples CG and MG, the only cells that were biopsied that had no deletion on the paternal side were samples two, which had a mutant maternal allele and therefore possible paternal A.D.O., eight and ten? 13:25:36 13:25:40 13:25:44 13:25:47 13:25:51 13:25:57

MR. HAMAD: I have an objection to this line of question, in that you stopped him from answering the question, the prior question, and also in the fact that I think you're asking the question -- 13:25:58 13:26:01 13:26:04 13:26:06 13:26:08

MR. LEUCHTMAN: No, I didn't stop him from answering the question. 13:26:09 13:26:10

MR. HAMAD: He wasn't finished. 13:26:11

MR. LEUCHTMAN: I encouraged him to answer the question and not to ramble on. 13:26:13 13:26:14

MR. STEIN: I object to the characterization of the Doctor rambling on. He's responding to your questions. 13:26:19 13:26:23 13:26:25

MR. LEUCHTMAN: Once encouraged, yes, I agree, and I'd like an answer to this one. 13:26:26 13:26:28 13:26:29

A. Okay. Column two, no deletion, sample number two; no deletion, sample 13:26:29 13:26:33

C. STROM, M.D., PhD.

number eight; no deletion sample number ten. 13:26:35 13:26:38

Q. What does no deletion mean? 13:26:38

A. It means, the Delta F 508 mutation was not observed in those samples. 13:26:40 13:26:46

Q. What does no amp mean? 13:26:50

A. No amp means no amplification. Means no analysis. 13:26:53 13:26:57

Q. Doctor, I'm going to ask you questions about two embryos, eight and ten and I want to make it clear it that I'm not asking whether one was more likely than the other, but whether you can say without engaging in guess, speculation, or conjecture that either one in and of itself was more likely than not the involved embryo. Do you follow me? 13:26:58 13:27:00 13:27:02 13:27:06 13:27:08 13:27:10 13:27:12 13:27:14 13:27:18

A. No. That's a stupid question. There are higher risks to one of these embryos than the other embryo, but that doesn't mean it's more likely than not to have been the one that caused the pregnancy. 13:27:19 13:27:22 13:27:25 13:27:28 13:27:32 13:27:34

Q. That's what I'm trying to ask 13:27:34

C. STROM, M.D., PhD.

you now. 13:27:36

A. There's no way to know which of those embryos resulted in the pregnancy. 13:27:36 13:27:39

Q. There's no way to know. 13:27:41

A. No. 13:27:44

Q. All right. Do you have an opinion as to the percentage chances of -- strike that. 13:27:49 13:28:44 13:28:48

Now, this is an issue we touched on earlier. Was it reasonable for Dr. Hughes to set as a condition to Genesis doing P.G.D. the undergoing by a couple of C.V.S. or amniocentesis? 13:28:51 13:28:58 13:29:01 13:29:05 13:29:08

A. A requirement? I don't think that's reasonable. 13:29:14 13:29:16

Q. As a precondition of his getting involved. 13:29:17 13:29:18

A. Well, that's up to him. It's his decision. 13:29:19 13:29:22

Q. Do you agree or disagree that it's important scientifically for a lab doing single cell P.G.D. to learn that there's been a failure or a misdiagnosis ten to fifteen weeks into a pregnancy as opposed 13:29:23 13:29:25 13:29:29 13:29:34 13:29:37

C. STROM, M.D., PhD.

to after the baby has been born? 13:29:41

A. No. 13:29:43

Q. Do you agree that as of early to mid 2004, Genesis consisted of scientists trying to develop a complicated single cell test? 13:29:44 13:29:49 13:29:52

MR. STEIN: I object to the form of the question. How is he supposed to know what was going on at Genesis Genetics? 13:29:58 13:29:59 13:30:02 13:30:04

MR. LEUCHTMAN: I guess especially now that he's coached, he can say I don't know. 13:30:04 13:30:07 13:30:10

MR. STEIN: You know, when you ask a question that is loaded with presumptions and assumptions that on its face is beyond the canon of anything who's not intimately involved in the operation of Genesis Genetics, the question speaks for itself as being inappropriate and if you couch it in those terms, you get an objection from me. 13:30:10 13:30:11 13:30:14 13:30:16 13:30:22 13:30:26 13:30:27 13:30:30 13:30:33 13:30:37

MR. LEUCHTMAN: Noted. 13:30:37

MR. STEIN: Thank you. 13:30:38

EXHIBIT 8

genesis
genetics institute
Genomics Technology Center of Michigan
5555 Conner Avenue, Suite A2064
Detroit, MI 48213
313-544-4006
PGD@GenesisGenetics.org

Grossbaum.M/C.CFTR10+11
July 18, 2004::07:22 PM
SB-assay - Exon 11 - G542X

DNA Sequencing – Genotyping Assay

Date:	18 July 2004
Case:	Morganstern-Grossbaum.M/C
Family:	110000814-2004
Assay:	CFTR – exon 11 Sequencing G542X, cNT1756 G>T
Sequencing:	Susan Brown, PhD
DNA Reads:	SB JK
Review/Approval:	MRH

Data concordant between runs. Exon 11 data look clear & unambiguous. Always concern for ADO (we should try to obtain untransferred embryos for next time assay)

EXHIBIT 9

Genomics Center at Samaritan
5555 Conner Avenue, A2064

Detroit MI
48213

Phone: 313-544-4006

Fax: 313-544-4006

Message :

Dear NYU IVF team

Attached are the final data for PGD results for your patients;
Chaya Morganstern & Menachem Grossbaum
PGD for a two mutations in the CFTR
July 2004 IVF cycle

This is a final report for this PGD cycle. A lab result sheet was sent to you at 10:30. We are disappointed with the results given the large number of amplification failures for one fo the two CFTR alleles. We note that many of the embryos are significantly behind in their development with only 3 and 4 cells today. This may be the reason so many of these samples produced only partial data. In fact, the dF508 allele did not amplify in most of this cohort of samples. Have most of these embryos arrested in development?

If the couple chooses a transfer with this partial data-set, those samples displaying the G-allele at G542X would be predicted unaffected, assuming no allele drop out. However, ADO is possible in compound heterozygote testing such as this, and even more likely given the embryo quality. Therefore, a follow-up amniocentesis or CVS would be essential in this setting. The couple understands this.

We would like to study further any samples that are untransferred or not frozen. While most are of poor quality and may not be helpful, it might be possible to examine them and enhance this test in the future should this couple undergo IVF again. In their informed consent they initialed both lines, so please check with them to see if donation is possible.

Call us if you have any questions whatsoever. Best number today: 313-544-4006, extension 6 (not a voice prompted choice).

Please give this nice couple our best regards.

Sincerely,
Mark Hughes

From: Genesis Genetics Institute	**To:** NY Univ Reproductive Medicine 2122630059 at 11:06 AM
Date: 7/19/2004	**Page(s):** 1

EXHIBIT 10

genesis
genetics institute
The Trowbridge Historial House
1380 East Jefferson Avenue
Detroit, MI 40207

tel/fax: 313-544-4006
www.genesisgenetics.com

Genesis Genetics Institute

Center for Preimplantation Genetics

PGD Transfer Report

Morganstern-Grossman.CFTR10+11.NYU.2004#316

July 19, 2004

NYU Reproductive Center
660 First Avenue, LC601
New York, NY 10016
Fax: 212-263-0059

Single cell molecular testing for cystic fibrosis – compound heterozygosity

Gene: CFTR **Locus ID: 1080** **Chromosome: 7q31.2** **OMIM: 219700; 602421**
HGNC: 1884 **SwissProt: P13569** **RefSeq: NM 000492** **Autosomal Recessive**

Name	Allele 1 (normal)	Allele 2 (mutant)
Chaya Morganstern-mat (1980-05-27)	Exon 11, G542X, Nt1756 G	Exon 11, G542X, Nt1756 T
Menachem Grossbaum-pat (1980-01-01)	Exon 10, ΔF508, cNT1652 CTT	Exon 10, ΔF508, cNT1652 delCTT

Sample Submission:

MorganSTern-GrossmanC/M.2004#316
Morganstern-Grossman.C/M.CFTR10+11.NYU.2004#316

Biopsy Date:	2004.07.17::11:00 ET
Sample Receipt:	2004.07.18::08:45 ET
Data Complete:	2004.07.19::10:15 ET
Lab e-Report :	2004.07.19::10:30 ET
Transfer Report:	2004.07.19::11:05 ET

Twenty (20) tubes were submitted for micro-genomic testing. Ten (10) were labeled as containing a single blastomere biopsied from ten (10) cleavage-stage IVF embryos produced by Chaya Morganstern and Menachem Grossbaum. Ten (10) additional tubes were labeled as containing media buffer only (B), obtained in parallel and included to monitor for potential exogenous DNA contamination.

This report continues

Sample Number	Embryo Quality 1 – 4 (1)	CFTR Exon 10 ΔF508 c1652 CTT / del CTT Paternal Alleles	CFTR Exon 11 G542X c1756 G > T Maternal Alleles	Interpretation
2	2 – 8 cell	CTT present	T-only	Unsafe; Possibly Affected – ADO Paternal
3	2 – 3 cell	No DNA signal	No DNA signal	No Molecular data produced by this cell
4	2 – 4 cell	No DNA signal	G	Partial Data Only; Normal Maternal Allele*
7	2 – 7 cell	No DNA signal	G	Partial Data Only; Normal Maternal Allele*
8	2 – 8 cell	CTT present	G / T	Predicted Heterozygote Carrier*
9	2 – 4 cell	No DNA signal	No DNA signal	No Molecular data produced by this cell
10	2 – 4 cell	CTT present	G / T	Predicted Heterozygote Carrier*
13	2 – 4 cell	No DNA signal	G	Partial Data Only; Normal Maternal Allele*
14	2 – 7 cell	No DNA signal	No DNA signal	No Molecular data produced by this cell
15	2 – 4 cell	No DNA signal	G	Partial Data Only; Normal Maternal Allele*
Controls				
CG maternal	Genomic DNA-5pg	CTT / [CTT]	G / T	Heterozygote Carrier of exon 11 mutation Parental DNA control; data as predicted
GR paternal	Genomic DNA-5pg	CTT / del CTT	G / [G]	Heterozygote Carrier of exon 11 mutation Parental DNA control; data as predicted
CFTR-10 Control	Genomic DNA-1 cell	CTT / del CTT	G / [G]	Heterozygote Carrier of exon 11 mutation Control DNA; data as predicted
CFTR-11 Control	Genomic DNA-1 cell	CTT / [CTT]	G / T	Heterozygote Carrier of exon 11 mutation Control DNA; data as predicted
Media	Blanks	No DNA signals	No DNA signals	No evidence of exogenous DNA

Interpretation and notes: A customized single-cell molecular assay was developed expressly for the CFTR alleles in this family. Chaya Morganstern and Menachem Grossbaum were each found on routine screening to be heterozygous (a carrier) for a mutation in the CFTR. They are at high genetic risk (25%) of transmitting both of these mutations, *in trans*, resulting in a child with cystic fibrosis.

This assay functioned well in the control samples displaying the normal and mutant alleles from the appropriate parental and control micro-DNA samples. Control algorithms produced the expected molecular data. No nucleotide signal was observed in the submitted media blanks.

It is noted that many of these embryos have only a very small number of cells at the time of biopsy. Only two of these embryos developed to the 8-cell stage at the time of biopsy, and many of the embryos had only half this number. This may explain the disappointing outcome in this analysis. Most of the samples did not produce data at the ΔF508 allele. Usually, when this occurs, it is not a DNA test issue, but pertains to the quality of the embryo or the biopsied cell from it. This assay performs with very high sensitivity and specificity when examining single lymphocytes, fibroblasts, amniocytes and one genome-equivalent of DNA. Analysis at this locus has been routinely performed since 1991 and it is a very robust assay. It performed well in the control samples processed in parallel during this testing. Often, when molecular data is not obtained, the embryo from which that blastomere was derived has developed poorly or arrested in development. It is presumed that intracellular nucleases degrade the genomic material for analysis. Other reasons for signal failure include: a) blastomere transfer issues; b) absence of an intact nucleus; c) partial degradation of the genome within the cell, and d) stochastic failure of the amplification reaction.

Allele Drop Out is a distinct concern in this sample set. *ADO is a stochastic phenomenon which has been reported by all laboratories performing single cell molecular testing. If one genomic allele is under represented in the amplification reaction, and not visualized, that allele "drops out" and could result in a misdiagnosis.

This report continues

This is an experimental research protocol. Chaya Morganstern and Menachem Grossbaum have acknowledged verbally and in writing that they understand that Preimplantation Genetic Diagnosis is not perfect technology, and that PGD is not considered routine medical care. They recognize that micro-genomic testing overnight of one cell, with two different DNA mutations, will likely never be as reliable as testing hundreds or thousands of cells from an amniocentesis or blood sample over the course of many days. They understand that there have been errors in the past in PGD by virtually all laboratory groups performing this technology, (including this laboratory) especially when testing for completely separate gene mutations (compound heterozygosity) in disorders like cystic fibrosis.

Chaya Morganstern and Menachem Grossbaum have been counseled extensively by multiple medical professionals. They understand that the goal in PGD is to reduce their likelihood of having a fetus with cystic fibrosis from the *a priori* risk of 25% to a value significantly less, but that *this risk is not reduced to zero*. Zero risk is not expected, is not promised, and is not possible in one-cell, one-gene, two-mutation testing overnight. Should a pregnancy ensue Chaya Morganstern has agreed to undergo conventional prenatal testing to confirm these microgenomic experimental results.

(electronically signed)
Mark R. Hughes, MD, Ph.D.

EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT

IN THE DISTRICT OF NEW JERSEY

----------/

CHAYA GROSSBAUM and MENCHEN GROSSBAUM, Her Spouse, Individually, and as Guardian ad litem of the Infant, ROSIE GROSSBAUM,

Plaintiffs,

-vs- Index No. 07-CV-359

GENESIS GENETICS INSTITUTE, LLC, OF THE STATE OF MICHIGAN, MARK R. HUGHES, M.D., NEW YORK UNIVERSITY SCHOOL OF MEDICINE, and NEW YORK UNIVERSITY HOSPITALS CENTER, both Corporations of the State of New York, ABC CORPORATIONS: 1-10 and John Doe,

Defendants.

_____/

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The Deposition of DR. MARK HUGHES,

Taken at 1380 Trowbridge Place,

Detroit, Michigan,

Commencing at 12:55 p.m.,

Friday, May 14, 2010
Before Laura J. Steenbergh, CSR-3707, RPR, CRR, RMR

APPEARANCES:

NUSBAUM, STEIN, GOLDSTEIN
BRONSTEIN & KRON, P.A.
Attorneys for Plaintiffs
20 Commerce Blvd.
Succasunna, NJ 070876
BY: LEWIS STEIN, ESQ.
BY: LYNN HARRISON, PARALEGAL

TROWBRIDGE LAW FIRM
Attorneys for Defendants
Genesis Genetics Institute, LLC
And Mark R. Hughes, M.D.
1380 East Jefferson Avenue
Detroit, Michigan 48207
BY: STEPHEN LEUCHTMAN, ESQ.
BY: ALI ZAIDI, ESQ.

APPEARANCES (Continued):

MARSHALL, DENNEHEY, WARNER
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New York University School of
Medicine and New York University
Hospitals Center
425 Eagle Rock Avenue, Suite 302
Roseland, New Jersey 07068
BY: JAY A. HAMAD, ESQ.

INDEX TO EXAMINATIONS

INDEX TO EXHIBITS

Detroit, Michigan
Friday, May 14, 2010
About 12:55 p.m.

DEPOSITION EXHIBITS P1 AND P2
WERE MARKED BY THE REPORTER
FOR IDENTIFICATION

MR. STEIN: Dr. Hughes, we're here today to take your deposition for the second time, since I have been in receipt of a letter dated March 2nd, 2010, addressed to Stephen F. Leuchtman, consisting of three pages, which we've marked for purposes of this deposition P1, and it would be Hughes 2, since we already had your deposition one time, and also a two-page bibliography, which I've marked P2 or had marked P2.

MR. LEUCHTMAN: It's not a bibliography.

MR. STEIN: That's my characterization. No, a biography. Did I say bibliography? I misspoke.

And which we've marked P2. And as a result of having received this letter and the advice that you plan to offer yourself as an expert witness in the event this matter goes to trial, we're here to take your deposition today on the basis of this recent submission.

DR. MARK HUGHES,

having first been duly sworn, was examined and testified on his oath as follows:

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MR. STEIN: Okay.
MR. LEUCHTMAN: I'm not telling him not to answer.
THE WITNESS: Oh. I'm now gun shy. Whenever you talk I don't know what to say.
Yes, there was. I was -- can I extrapolate? I was recruited to the NIH and Georgetown University because of my research in embryo science, and did significant amounts of work there, and gave major lectures at the NIH and at Georgetown, and taught on the subject, and was quite publicly known. Then there was a change in the administration of Washington. The republicans took the house for the first time in decades, and Newt Gingrich was the speaker of the house, and the philosophy of doing anything whatsoever with an embryo anywhere near the NIH became of a concern because we were all very actively trying to double the NIH budget at the time. So we were all busy lobbying to get more money for biomedical research. And so suddenly I became a liability in that quest.
BY MR. STEIN:
Q. And so they asked you to leave?
A. Yes. Well, they said I could stay, but I couldn't work on this. And then the good Jesuits were now in the public eye, and they became concerned because it was

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obvious what was going on, and so --
Q. Did you continue to work with embryos after it became government policy not to allow that type of research at the NIH?
A. I don't know anything about the policies of when it was or when it wasn't. What I know is that when the decision was made that we shouldn't do this at the NIH, or have a faculty member -- or, not a faculty member -- a staff member of the NIH doing it even across the street at the Samaritan Hospital because of the political issues involved, I was asked to resign.
Q. Were you using NIH offices to conduct the research that you were doing contrary to government policy?
A. No. I was using the offices at Georgetown.
Q. Okay. Now, turning to your deposition, Exhibit P1, which is your report, three-page report, in the paragraph before the bottom of the first page that begins, I spoke with the Grossbaums and conducted the interview that you have described in your report, I take it that that conversation lasted for some time?
A. They usually last a good hour, sometimes longer.
Q. Okay. Now, that is, obviously, direct contact between you and what would become your patient when they sent the laboratory materials from NYU, is that correct?
A. Not exactly.

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Q. Okay. And I take it that you suggested that is not a contact with a patient in the sense that a doctor has contact with patients, is that correct?
A. In general laboratories never talk to patients. They do the test that was ordered, they write a report, they send it to the person who ordered the test, and that's the extent of it. In the field of PGD, the few of us that do this feel that it's more important to communicate beforehand with the patient about the risks and benefits of the procedure. Because sometimes the doctors at the clinics don't necessarily know the nuances of the latest. They're IVF experts, not genetic experts. So from a perspective of an informed consent, we take and go the extra mile and spend time with them, a significant amount of time with them, explaining to them the steps involved.
Q. Now, have you ever encountered the issue with regard to practicing medicine in the State of Michigan under its rules and regulations for the medical profession?
MR. LEUCHTMAN: Encountered what issue? Object to the form of the question as vague and ambiguous.
MR. STEIN: I'll rephrase it.
BY MR. STEIN:
Q. Has the issue ever been raised with the regulatory authorities in Michigan who regulate the practice of medicine as to whether or not the contacts that you have

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with the patient constitutes practicing medicine?
A. I don't have a license in Michigan to practice medicine. I don't practice medicine. I happen to have an MD, but what I do is science, it's my PhD. I don't practice medicine.
Q. And you don't consider the providing informed consent to the patient who's going to be a prospective submitter of materials for laboratory analysis to be practicing medicine, is that right?
A. Not even remotely. It's more like a genetic counselor. That's why we don't talk to the patient during or after the case.
Q. Okay. Now, when you said -- and you have a copy of your letter in front of you?
A. Yeah.
Q. And you say in that paragraph that -- you explained, to quote you, I explained the technology involved isn't perfect and pushes medical diagnostic technology to its absolute limit.
Can you tell me what you mean by that?
A. Yes. Unlike testing that's done in almost any other field of medicine, we're studying the smallest unit of life, one cell. And we're studying it for the smallest unit of inheritance, one gene. And we're studying it for the smallest possible part of a gene, changes of a single

11 (Pages 38 to 41)

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Q. -- to CVS or amnio in advance, is that right?
A. No. No. So first of all, I don't do any referring, because the patient isn't mine. The patient belongs to the clinic and the doctor who's taking care of them. So we would tell that doctor -- as far as I would go is I would tell the patient that we wouldn't be able to help them, that there may be other laboratories who would, that we will communicate this back to their physician, and then they can decide where to go, but we can't help them.
Q. So is it your testimony that you were not aware whether or not the other laboratories that you mentioned, RGI or the laboratory in Virginia, would do a PGD study on a couple that did not agree to do amnio or CVS, is that your testimony?
A. I don't know what their policy would be in a given case, depending on the rarity of the mutation, the type of mutation, the number of samples that would be available. I don't know what their policies would be.
Q. We're talking strictly about a policy that you indicated exists at Genesis Genetics at that time, and I take it to the present.
A. That's correct.
Q. That you will not have taken a case if the couple do not agree to undertake CVS or amnio following the IVF

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procedure, is that correct?
A. That's correct.
Q. That's your policy?
A. That's our policy.
Q. And you were not aware, either at the time that you saw the Grossbaums or even today, as to whether or not the other laboratories that do the kind of PGD studies that you do would do those studies without a commitment for the people to undertake amnio or CVS, is that correct?
A. I do not -- I can't comment on the policies of the other places, and I'm not aware of it.
Q. Okay. And is it your testimony that you yourself would not have been referring anyone to these laboratories, it would have to be the doctor that --
A. Right. Because the patient, if I was to tell NYU that I've referred their patient to another laboratory, they'd have a fit, and rightfully so.
Q. Okay. So then you've never referred then to organizations who did not require conventional prenatal follow-up, testing, amnio or CVS, is that right?
A. I don't refer patients to anywhere. I tell patients that -- and there's about three or four a month -- I tell them we're unable to help you, and I explain why. And I say we will talk with your doctors and there are other laboratories that might be able to help you.

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Q. Okay. And this was the practice at the time that the Grossbaums had their studies?
A. Yes.
Q. And this is a status that you've always known to be the case, is that right? I'll withdraw that question. That's a vague question.
Well, can you tell me then, Doctor, why at the top of page two of your report, P1, I read the following statement, I have had people over the years voice objection to amnio or CVS, and when this has happened I have referred them to organizations who did not require conventional prenatal follow-up testing with amnio or CVS.
Can you tell me how you could write that in a report and yet testify the way you have here today?
A. I'm not specifically referring the patient to another organization. That's incorrectly stated. I've never referred a patient to another center. I give them options through their doctor.
Q. Okay. Now, you've also indicated in your report that you discuss the risk of misdiagnosis, is that correct?
A. Yes.
Q. And -- give me a second.
All right. Doctor, I believe you indicated in your prior deposition that the risk of misdiagnosis was

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between three and five percent, is that correct?
A. That's the risk that's quoted around the world in other PGD programs, and in general the genetic counselors quote that number. In our group it isn't that high, but that's the number that's been sort of announced by --
Q. Okay. Can you tell me, when you say that's announced by other groups and around the world, where are these announcements made? What specifically are you referring to?
A. So at scientific meetings people stand up and talk about the error rates that they see.
Q. And you have a specific recollection of people standing -- of particular people standing up?
A. Sure.
Q. Okay. What group or what person in these meetings do you recall standing up and they have an error rate of three to five percent?
A. They don't necessarily say that they have an error rate. They quote that as the rate in the field.
Q. Okay.
A. And I've always thought that was high.
Q. Okay. In other words, individuals have stated at meetings, who are attending the meetings and are working in the field, that the error rate in the field in general is three to five percent, is that correct?

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A. I've heard that many times.
Q. Okay. And has that error rate changed over time?
A. Actually the quoted numbers from just last week at the international meetings were still three to five percent.
Q. Okay. So someone got up and quoted three to five percent at the meeting last week?
A. I heard it discussed, yes.
Q. Okay. And who did you hear it discussed from? Who said it?
A. I'd have to go look.
Q. And where would you look?
A. I'd look at the minutes of the meeting that we just had.
Q. And those minutes are circulated?
A. No. They're notes that I would have taken. Or they might be in the abstract. We can look.
Q. And is the abstract circulated for everybody who's in attendance at the meeting?
A. Yes.
Q. And what was the nature of the meeting, what was the group that met?
A. The PGD International Society.
Q. And where was the meeting?
A. France.
Q. And was Dr. Xu there?
A. No.

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Q. And your rate is less than one-half of one percent, is it not?
A. No. Our rate runs between one and two, depending on the year.
Q. So each year you have one to two percent misdiagnosis?
A. 1.2, 1.3, 1.4, 1.5.
Q. Now, is that specifically with respect to cystic fibrosis, or is that with respect to all --
A. No. That's all diseases.
Q. And how many do you do a year?
A. I can tell you what we did in 2004.
Q. How many did you do in 2004?
A. I wrote the numbers down. We did 582 cycles.
Q. And you have that specifically available to you, you wrote it down?
A. I wrote it down before I came over here. Because I figured you'd ask.
Q. Okay. And what did you write it down on?
A. (No response).
Q. What did you write it down on?
A. I just wrote it in the corner here on this piece of paper.
Q. Before you came over here?
A. No. I had it in my mind. But I knew the question was coming, so I scribbled it over here so I wouldn't forget

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the numbers.
Q. And do you know how many you did in 2009, last year?
A. No. But almost twice that.
Q. And how many failures did you have in 2004?
A. Three.
Q. The Grossbaums was one of them?
A. Yes.
Q. And what was the analysis done on the other two that had failed?
A. One of them was a healthy child that we predicted was a carrier, and one of them was an affected that was picked up on amniocentesis or CVS.
Q. And was it picked up?
A. Yeah.
Q. And did the parents abort in that case?
A. I don't remember. There's no link between those. An amniocentesis is not a search and destroy mission.
Q. I think we explored that at the last deposition, didn't we?
A. I don't remember.
Q. You haven't read your deposition --
A. Months ago.
Q. -- prior to coming here today?
A. No.
Q. The 582 cycles that you described, were they for all

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forms of genetic disorders, or just for cystic fibrosis?
A. No. For all forms.
Q. Now, the Grossbaums were described as having a mutation that was -- can be said to be compound heterozygous, is that right?
A. Yes.
Q. Do you know how many of the cystic fibrosis studies that you did in 2004 were for couples who had compound heterozygous mutations?
A. I don't know those numbers off my head, no.
Q. Do you know how frequently you see compound heterozygous mutations to be analyzed?
A. Fairly frequently. Now.
Q. Now?
A. Um-hum (affirmatively).
Q. How about in 2004?
A. We would see them then, too, but it's gone up substantially, the numbers. Because the ability to find the mutations in these different diseases has gone up, because the technology for looking for the mutations is easier. So just a few years ago there weren't very many places that would -- well, cystic fibrosis is different -- but for many of these disorders there wasn't anyone who was willing to screen by DNA sequencing the entire gene looking for what the other mutation might be, so PGD

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what you represent to be your formal report?
MR. HAMAD: Objection to form.
THE WITNESS: It's our formal report.
BY MR. STEIN:
Q. And that is your complete report on the Grossbaums' matter?
A. Yes.
Q. Okay. Now, turning to the P8 -- do you have a copy in front of you?
A. Yes.
Q. In the first paragraph of P8 you describe the results as disappointing, is that correct?
A. Yes.
Q. And then you go on in your second paragraph to say, if the couple chooses a transfer with this partial data set, do you not?
A. Um-hum (affirmatively).
Q. Does that statement assume that the couple will be advised that there is only a partial data set?
MR. HAMAD: Objection to form.
THE WITNESS: I'm not assuming anything.
BY MR. STEIN:
Q. Well, for the couple to choose to transfer this partial data set there has to be some communication to them that there is a partial data set that was disappointing,

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doesn't there?
MR. HAMAD: Objection, form. Misstates his prior testimony. You can answer.
BY MR. STEIN:
Q. Go ahead.
A. I'm not sure I understand. We're dealing with an outstanding group of people who understand PGD very well. They're going look at this table and see that --
Q. Doctor, my question --
MR. STEIN: Can I have the last question read back please?
(Record repeated as requested).
THE WITNESS: When a doctor reads a diagnostic report that they receive, they read it and understand what it says. I mean, that's why they order the test. So you send them the information, whichever one you want, and it's pretty clear that there's a partial data set. It doesn't take rocket science to see that.
BY MR. STEIN:
Q. Doctor, my question just called for a yes or no answer.
A. Then I don't understand the question.
Q. All right. If, as you say in your message, a document we marked P8, if the couple chooses a transfer with this partial data set, you are referring to a choice made by the couple who you provided laboratory services to, are

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you not?
A. I'm referring to the choice that the couple would make after hearing the information about the quality of their embryos, and the molecular results and the options that they have in front of them about what they would like to do. And it isn't necessarily so, I mean, I don't know, but it isn't necessarily so that the clinic would agree to what that would be. They might and they might not.
Q. Might agree and might not agree to what?
A. Well, if the doctor said we're not going to transfer this embryo, some clinics would say we're not going to transfer the embryo. Other clinics would say, well, no, the embryo belongs to you and you can take it if you wish. I stay away from those things, but I point out the limitations of the testing.
Q. Are you presuming by that comment that the couple will be advised of the disappointing result of your test?
MR. HAMAD: Objection to form, asked and answered.
THE WITNESS: I'm not assuming anything.
BY MR. STEIN:
Q. Okay. Now, you say that in that message that AVO is possible in compound heterozygous testing such as this, and even more likely given the embryo quality. That's what you write, is that right?

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A. Yes.
Q. Now, in the preliminary report that you sent, as you described it, we've marked P5, you discuss allele dropout, don't you?
A. Yes. Well, I mentioned it in -- it's mentioned in sample two.
Q. Now, just so I'm clear, is it not anticipated that the clinic will proceed with IVF based on the form of report that is present and marked P5?
MR. HAMAD: Asked and answered, three questions ago.
THE WITNESS: This report is sent to them just like any laboratory report. They review it, they make a decision in the best interests of the patient, I hope, and I don't have any assumptions about which ones they're going to transfer. In fact, earlier this week a couple elected to take two embryos that were affected, so --
BY MR. STEIN:
Q. Aside from what the couples intend to do as a result of the decision, you are presuming when you send P5 that the fertility clinic will act on the content of the information contained in P5, are you not?
A. No. I'm sending them information. What they do with it at that point is completely up to them. They can say we don't like any of this, they can say we're going to

EXHIBIT 12

CURRICULUM VITAE

Charles M. Strom, M.D., Ph.D., F.A.A.P., F.A.C.M.G., H.C.L.D.

COLLEGE:	Yale University, New Haven, Connecticut Department of Molecular Biophysics and Biochemistry, B.S., June 1973, Cum Laude
GRADUATE SCHOOL:	University of Chicago, Chicago, Illinois Department of Biology, Ph.D., December 1977
PROFESSIONAL SCHOOL:	University of Chicago Pritzker School of Medicine, Chicago, Illinois. M.D., June 1979 with Honors
RESIDENCY:	University of California Medical Center, San Diego, California. Department of Pediatrics, July 1979 - June 1982
FELLOWSHIP:	University of California Medical Center, San Diego, California. Pediatric Genetics and Metabolism, William L. Nyhan, M.D., Ph.D., Chairman, 1981-1982
BOARD CERTIFICATION:	American Board Pediatrics, 1985 American Board of Medical Genetics - General, 1987 American Board of Medical Genetics - Clinical Genetics, 1987 American Board of Medical Genetics, - Clinical Biochemical Genetics, 1987 American Board of Medical Genetics, - Clinical Molecular Genetics, 1993 (Recertification, 2003) American Board of Bioanalysis - High Complexity Laboratory Director, 1995
LICENSURE:	Licensed Physician and Surgeon: Illinois Licensed Physician and Surgeon: California Certificate of Qualification, Laboratory Director New York State: Molecular Testing, Biochemical Testing, Maternal Serum Screening Laboratory Director: State of California, Molecular Genetics
PREVIOUS APPOINTMENT:	Instructor, University of Chicago, Department of Pediatrics, Chicago,

	Illinois, July 1, 1982 - July 1, 1984 Assistant Professor, University of Chicago, Department of Pediatrics, Committee of Genetics, Committee of Developmental Biology and in the College, Chicago, Illinois, July 1, 1984 - May 1, 1988
APPOINTMENT:	Director, Medical Genetics and DNA Laboratory, Departments of Pediatrics and Obstetrics and Gynecology Illinois Masonic Medical Center 836 W. Wellington, Chicago, Illinois 60657, (773) 296-7095 May, 1988 – October, 2000
	Academic Appointment Assistant Professor, Department of Obstetrics and Gynecology, Rush Medical College September, 1994 – October, 2000
	Medical Director, Molecular Genetics and Biochemical Genetics Laboratories Nichols Institute, Quest Diagnostics 33608 Ortega Highway San Juan, Capistrano, CA 92675 949-728-4701 October 2000 – June 2002
CURRENT APPOINTMENT:	Medical Director, Genetic Testing Center Nichols Institute, Quest Diagnostics 33608 Ortega Highway San Juan, Capistrano, CA 92675 949-728-4701 June 2002 - present
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TEACHING EXPERIENCE:	Co-Instructor BioSci. 236, "Vertebrate Developmental Biology", University of Chicago, Chicago, Illinois, Spring 1979 Instructor, BioSci. 243 "Principles of Human Genetics", University of Chicago, Chicago, Illinois, Spring 1983, Autumn 1983 Autumn 1984 and currently Instructor, Medical Genetics, University of Chicago, Illinois, Spring 1984-1988 Co-instructor with Dr. Aron Moscona, Biology of Vertebrate Development, Winter 1984, 1985
DOCTORAL RESEARCH:	"Molecular Biology of Chick Cartilage Differentiation", Department of Biology, University of Chicago, Chicago, Illinois
POSTDOCTORAL RESEARCH:	"Molecular Biology of Friend Erythroleukemia Erythroid Differentiation", Scripps Clinic and Research Institute, La Jolla, California, Dr. John Yu, Sponsor
AWARDS:	Alpha Omega Alpha National Medical Honor Society, June 1979 John Van Prohoska Award for "Outstanding Potential in Teaching, Research and Clinical Medicine", University of Chicago, June 1979 Mosby Book Award for "Outstanding Performance as a Senior Medical Student", University of Chicago, June 1979 Ross Award in Research for Pediatric House Officer presented by the Western Academy of Pediatric Research for "Contribution to Research in Pediatrics", Carmel, California February 1981 Sigma Xi, June 1984 Hartford Fellowship, 1984-1987 Schweppe Fellowship, 1984-1987

GRANT SUPPORT:	Summer Research Training Grant, University of Chicago, June 1973 - October 1973. Medical Scientist Training Grant, National Institutes of Health, January 1974-1979 Sprague Memorial Institutional Grant, October 1982 and 1983 American Cancer Society Institutional Grant, October 1982 Children's Research Institutional Grant, 1982 and 1983 March of Dimes Basil O'Conner Research Grant, September 1983 - August 1985; $72,000 John A. Hartford Fellowship, July 1984 - July 1987; $105,000 Kennedy Mental Retardation Research Center. Career Development Grant July 1984 - June 1987; $96,000 Schweppe Fellowship July 1984 - June 1987; $45,000 NIH - R23 Award July 1984 - June 1987; $36,000/year March of Dimes Research Grant April 1, 1986 - April 1, 1988; $35,000/year Genetics Screening Fund (Private Donations); $46,000
MEMBERSHIP IN STATE COMMITTEES:	President, Genetics Task Force of Illinois October 1985 - October 1986 Genetics Task Force of Illinois Governor's Advisory Committee on Inherited Metabolic Diseases, 1990 – 1998
MEMBERSHIP IN REGIONAL NETWORKS:	Steering Committee, Great Lakes Regional Genetics Network 1985 - 1986 Chairman of Subcommittee of Quality Assurance in Biochemical Genetics Testing of the Great Lakes Regional Genetics Network October 1985 - October 1986 Co-Chairman of Subcommittee for Quality Assurance in DNA Laboratories, 4/92-4/97

MEMBERSHIP IN NATIONAL COMMITTEES:	American Society of Human Genetics Committee on Social Policy, December, 1994 Subcommittee for Genetic Testing in Children, December, 1994 – 1998 American College of Medical Genetics Cystic Fibrosis Screening Committee March 2002 - present
MEMBERSHIP IN SCIENTIFIC SOCIETIES:	American Society of Human Genetics Association of Molecular Pathology
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MEMBERSHIP IN MEDICAL SOCIETIES:	The Chicago Gynecological Society, January, 1995
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PATENT APPLICATIONS:	U.S. Patent Application No.: 11/554,293 Filing Date: 10/05/2006 Title: NUCLEIC ACID SIZE DETECTION METHOD Inventor(s): Huang et al. (Capillary Southern Analysis, An automated high throughput method for population based carrier detection of Fragile X Syndrome) U.S. Patent Application No.: 11/566,174 Filing Date: 12/1/2006 Title: METHODS OF DETECTING TPMT MUTATIONS Inventor(s): Charles M. Strom et al.
INTERNAL AWARDS:	Aggressive Innovation, Quest Diagnostics, 2002 Medical Innovation, Quest Diagnostics, 2006 Patent Innovation Award, Quest Diagnostics, 2006 Patent Innovation Award, Quest Diagnostics, 2007

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Cases that Dr. Strom has Testified In

In all cases qualified as expert in Genetics and DNA testing.

People v. Rudding, Cook County, IL. June, 1997

People v Buss, May, 1996 - Will County, IL

People v. Johnson, 1994 - Kane County, IL

Johnson v. Johnson, 1993 - Cook County, IL

People v. Birch, 1993 - DuPage County, IL

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